1. (Amended) An isolated nucleic acid molecule comprising the nucleotide sequence of SEQ ID NO:1.

2. (Amended) An isolated nucleic acid molecule comprising a sequence that:
(a) encodes the amino acid sequence shown in SEQ ID NO: 2; and
(b) hybridizes under highly stringent conditions to the nucleotide sequence of SEQ ID NO: 1 or the complement thereof.

RESPONSE

I. Status of the Claims

Claims 1 and 2 have been amended. No new claims have been added. Claims 1-4 are therefore presently pending in the case. For the convenience of the Examiner, a clean copy of the pending claims is attached hereto as **Exhibit A**. In compliance with 37 C.F.R. § 1.121(c)(1)(ii), a marked up copy of the original claims is attached hereto as **Exhibit B**.

II. Support for the Amended Claim

Claim 1 has been amended to further clarify the claim, and to recite that the isolated nucleic acid molecule comprises the nucleotide sequence of SEQ ID NO:1. Support for this claim can be found throughout the specification as originally filed, with particular support being found at least in Claim 1 and SEQ ID NO:1 as originally filed as well as in Section 5.1.

Claim 2 has been amended to further clarify the claim, and to recite highly stringent conditions. Amendment of Claim 2 finds support throughout the specification as originally filed, with particular support and a definition of highly stringent hybridization being found at page 4, lines 1-7.

As the amendments to Claims 1 and 2 are fully supported by the specification and claims as originally filed, they do not constitute new matter. Entry therefore is respectfully requested.

III. Claim Objection

The Action objects to the sequence listing allegedly because of the lack of adequate description. Although Applicants believe that the sequence listing as originally filed was reasonably clear, in order to further clarify the sequence listing the following information is provided. The nucleic acid of SEQ ID NO 1 encodes the amino acid of SEQ ID NO:2. The nucleic acid of SEQ ID NO 3 encodes the amino acid of SEQ ID NO: 4. The nucleic acid of SEQ ID NO 5 encodes the amino acid of SEQ ID NO: 6. The nucleic acid of SEQ ID NO 7 encodes the amino acid of SEQ ID NO: 8. The nucleic acid of SEQ ID NO 9 is the nucleic acid sequence of SEQ ID NO:1 with surrounding 5' and 3' regions. Having further clarified the sequence listing, Applicants therefore respectfully request that the objection to the sequence listing be withdrawn.

IV. Rejection of Claims 1-4 Under 35 U.S.C. § 101

The Action rejects claims 1-4 under 35 U.S.C. § 101, allegedly because the claimed invention lacks support by either a specific and substantial asserted utility or a well established utility. Applicants respectfully traverse.

The present invention has a number of substantial and credible utilities. The Action states (page 3, line 4-7) that based on a quote, that appears in a single non-peer reviewed "news" article, that "The state of the art in protein science indicates that it is impossible to predict protein functions solely with structure homology. "Identical structural features, or folds, in proteins can perform many different roles and so using only homology to predict function is a "very dangerous and difficult mission" (Apoorva Mandavilli, *Protein folds shield different roles*, BiomMednet News, November 1, 2001: internal quote from Janet Thornton). However, later in the very same article the same woman is noted to have said that "Function is also likely to change once sequence identity dips below 40%". This strongly suggests that Janet Thornton believes that once sequence identity dips below 40%, predicting protein function becomes less reliable (stated, rather dramatically, as a "very dangerous and difficult mission").

While prediction of protein function below the 40% sequence identity level may well be a tricky task, Applicants do not agree that in general the state of the art in protein science indicates that it is impossible to predict protein functions based solely on structural homology, particularly when such homology is significantly greater than 40%. The prediction of function based on the presence of functional domains is well recognized by those of skill in the art. Therefore, it is the Applicants' position

that those of skill in the art would find our assertion that the present invention is a CD20 and IgE receptor like protein to be credible. The Sequences of the present invention demonstrate high levels of homology over shared domains with annotated sequences present in the leading scientific repository for biological sequence data (GENBANK). These sequences have been annotated by third party scientists wholly unaffiliated with Applicants as encoding CD20 or IgE receptor like molecules. Examples of such sequences include but are not limited to Bonaldo, 1998 (EMBL accession number AI149899, IDS Cite No. BZ); Chaker *et al.*, 1994 (EMBL accession number XP002174357, IDS Cite No. CA); Ishibashi *et al.*, 2000 (EMBL accession number AB013103, XP002174360, IDS Cite No. CB); Hulett *et al.*, 2001 (EMBL accession number XP000993330, IDS Cite No. CC). Therefore, it is clear that there can be no question that those skilled in the art clearly believe that the described sequences encode CD20 or IgE receptor like molecules.

CD20and IgE receptor like proteins are known to be cell surface markers, receptors, and mediators of signal transduction and to play a role in the activation and release of agents that mediate a variety of allergic and inflammatory reactions, and as such, CD20 and IgE receptor like proteins have been subject to intense scrutiny as drug targets, for example, by Tanox, Inc. which is developing anti-IgE receptor antibody therapies for asthma and allergies. Therefore, the identification of a new and novel human CD20 and IgE receptor like protein has great utility.

Although the above discussion is believed to be dispositive of the utility issue, the Applicants would like to further direct the Examiner's attention to the parts of the specification (Sections 5.0 and 5.1) that describe the use of sequences in a gene chip format to provide a high throughput analysis of the relevant cellular "transcriptome".

Evidence of the "real world" substantial utility of the present invention is provided by the fact that there is an entire industry established based on the use of gene sequences or fragments thereof in a gene chip format. Perhaps the most notable gene chip company is Affymetrix. However, there are many companies which have, at one time or another, concentrated on the use of gene sequences or fragments, in gene chip and non-gene chip formats, for example: Gene Logic, ABI-Perkin-Elmer, HySeq and Incyte. In addition, two such companies (Agilent acquired by American Home Products and Rosetta acquired by Merck) were viewed to have such "real world" value that they were acquired by large pharmaceutical companies for significant sums of money. The "real world" substantial industrial utility of gene sequences or fragments would, therefore, appear to be widespread and well established.

The sequences of the present invention describe a novel gene encoding a CD20 and IgE receptor like protein and provide a unique identifier of the corresponding gene. Such gene chips clearly have utility, as evidenced by hundreds of issued U.S. Patents, such as U.S. Patent Nos. 5,445,934, 5,556,752, 5,744,305, 5,837,832, 6,156,501 and 6,261,776. The present nucleotide sequences clearly encode a novel human CD20 and IgE receptor like protein, as detailed throughout the specification. The specification also teaches that CD20and IgE receptor like protein are associated with cell surface markers, receptors, and mediators of signal transduction and may play a role in the activation and release of agents that mediate a variety of allergic and inflammatory reactions, and as such, CD20 and IgE receptor like proteins have been subject to intense scrutiny as drug targets, for example by Tanox, Inc., (and it's extensive U.S. patent portfolio) which is developing anti-IgE receptor antibody therapies for asthma and allergies. Therefore, as the present sequences are specific markers of the human genome, and such specific markers are targets for the discovery of drugs that are associated with human disease, those of skill in the art would instantly recognize that the present nucleotide sequences would be an ideal, novel candidate for assessing gene expression using such gene chips.

The Examiner is further requested to consider that, given the huge expense of the drug discovery process, even negative information has great "real world" practical utility. Knowing that a given gene is not expressed in medically relevant tissue provides an informative finding of great value to industry by allowing for the more efficient deployment of expensive drug discovery resources. Such practical considerations are equally applicable to the scientific community in general, in the time and resources that are not wasted chasing what are essentially scientific dead-ends (from the perspective of medical relevance). Clearly, compositions that enhance the utility of such gene chips, such as the presently claimed nucleotide sequences, must in themselves be useful. Moreover, the presently described novel CD20 and IgE receptor like protein provides uniquely specific sequence resources for identifying and quantifying full length transcripts that were encoded by the corresponding human genomic locus. Accordingly, there can be no question that the described sequences provide an exquisitely specific utility for analyzing gene expression.

Yet another example of the utility of the present invention is in expanding the utility of data coming from the human genome project. Persons of skill in the art, as well as thousands of venture capitalists and investors, readily recognize the utility, both scientific and commercial, of genomic data in general, and specifically human genomic data. All current therapeutics directly or indirectly interact

with biological sequences encoded by the human genome, and virtually all future human therapeutics shall do likewise. Consequently, billions of dollars have been invested in the human genome project, resulting in useful genomic data (see, *e.g.*, Venter *et al.*, 2001, Science *291*:1304). The results have been a stunning success, as the utility of human genomic data has been widely recognized as a great gift to humanity (see, *e.g.*, Jasny and Kennedy, 2001, Science *291*:1153). Clearly, the usefulness of human genomic data, such as the presently claimed nucleic acid molecules, is substantial and credible (worthy of billions of dollars and the creation of numerous companies focused on such information) and well-established (the utility of human genomic information has been clearly understood for many years).

Although Applicants need only make one credible assertion of utility to meet the requirements of 35 U.S.C. § 101 (*Raytheon v. Roper*, 220 USPQ 592 (Fed. Cir. 1983); *In re Gottlieb*, 140 USPQ 665 (C.C.P.A. 1964); *In re Malachowski*, 189 USPQ 432 (C.C.P.A. 1976); *Hoffman v. Klaus*, 9 USPQ2d 1657 (Bd. Pat. App. & Inter. 1988)), as a further example of the utility of the presently claimed polynucleotides, the Examiner is respectfully reminded that only a minor percentage of the genome actually encodes exons that in-turn encode polypeptide sequences. The presently described cDNAs provide biologically validated empirical data (*e.g.*, showing which sequences are transcribed, spliced, and polyadenylated) that *specifically* define that portion of the corresponding genomic locus that actually encodes exon sequence. Equally significant is that the described cDNA sequences define which exons are actually spliced together to produce an active transcript (*i.e.*, such sequences are generally required to conclusively identify functional exon splice-junctions). The Applicants submit that one skilled in the art would have clearly understood that the above *substantial and specific* utilities as inherent features of the presently described sequences.

For the many reasons described above, the present invention clearly has specific, substantial, credible and well established utility. Therefore, Applicants submit that the rejection of Claims 1-4 under 35 U.S.C. § 101 has been overcome and the Examiner is respectfully requested to withdraw the pending rejection of Claims 1-4 under 35 U.S.C. § 101.

V. Rejection of Claims 1-4 Under 35 U.S.C. § 112, First Paragraph

The Action rejects claims 1-4 under 35 U.S.C. § 112, first paragraph, since allegedly one skilled in the art would not know how to use the claimed invention, as the invention allegedly is not supported by a specific, substantial, and credible utility or a well-established utility. Applicants

respectfully traverse.

Applicants submit that as claims 1-4 have been shown to have a specific, substantial, credible and well established utility, as detailed in section IV above. Applicants therefore respectfully request that the rejection of claims 1-4 under 35 U.S.C. § 112, first paragraph, be withdrawn.

Claim 1 stands rejected under 35 U.S.C. § 112, first paragraph as failing to provide "sufficient guidance and information regarding the structural and functional requirements commensurate with what is encompassed by the instant claim." (The Action at page 5-6) because Claim 1 is alleged to recite a genus of polynucleotides of any size that has at least 24 contiguous nucleotides of SEQ ID NO: 1. While Applicants do not agree with the Action's position regarding the rejection of Claim 1 under 35 U.S.C. § 112, first paragraph for both written description and enablement, amendment of Claim 1 has rendered this argument moot and thus the rejection of Claim 1 under 35 U.S.C. § 112, first paragraph has been avoided by Applicants' amendment of Claim 1. Accordingly, the Examiner is respectfully requested to withdraw the pending rejection of Claim 1 under 35 U.S.C. § 112, first paragraph.

VI. Rejection of Claims 1 and 2 Under 35 U.S.C. § 112, Second Paragraph

The Action rejects claims 1 and 2 under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the invention.

The Action rejects Claim 1 as being allegedly vague and indefinite because it recites the term "NHP polynucleotide". Although Applicants believe that this claim as originally filed sufficiently points out and distinctly claims the invention, in order to more rapidly progress the case to allowance, Applicants have amended Claim 1 to remove the term "NHP polynucleotide". Applicants respectfully submit that this rejection has thus been avoided by Applicant's amendment of Claim 1, therefore the Examiner is respectfully requested to withdraw the pending rejection of Claim 1 under 35 U.S.C. § 112, second paragraph.

The Action rejects Claim 2 as allegedly indefinite based on the term " hybridizes under stringent conditions". Although Applicants believe that this claim as originally filed sufficiently points out and distinctly claims the invention, in order to more rapidly progress the case to allowance, Applicants have amended Claim 2 to specify "highly" stringent conditions. Highly stringent conditions for full length molecules are defined in the specification on page 4, lines 1-7. Applicants respectfully submit that this rejection has thus been avoided by Applicant's amendment of Claim 2 to specify "highly" stringent

conditions. Accordingly, the Examiner is respectfully requested to withdraw the pending rejection of Claim 2 under 35 U.S.C. § 112, second paragraph.

VII. Rejection of Claim 1 Under 35 U.S.C. § 102(a)

The Action rejects Claim 1 under 35 U.S.C. § 102(a), as being allegedly anticipated by *Hiller et al.*, (EMBL, accession number AA436088, November 9, 1997) and a second nucleotide sequence Applicants believe from the bottom of page 9 of the Action to be *Bonaldo* (EMBL, accession number AI149899, October 1, 1998) which teach a nucleotide sequence comprising at least 24 contiguous nucleotides of SEQ ID NO:1. While Applicants do not necessarily agree with the present rejection, as Claim 1 has been amended to recite comprising the full length of the nucleotide sequence of SEQ ID NO:1, Applicants submit that the rejection of Claim 1 under 35 U.S.C. § 102(a) as being anticipated by *Hiller et al.* and *Bonaldo* has been thus avoided and respectfully request withdrawal of the pending rejection of claim 1 under 35 U.S.C. § 102(a).

VIII. Conclusion

The present document is a full and complete response to the Action. In conclusion, Applicants submit that, in light of the foregoing remarks, the present case is in condition for allowance, and such favorable action is respectfully requested. Should Examiner Li have any questions or comments, or believe that certain amendments of the claims might serve to improve their clarity, a telephone call to the undersigned Applicants' representative is earnestly solicited.

This response is timely filed and Applicants believe no fees are due in connection with this response. However, should this be incorrect the Commissioner is authorized to charge any required fees or credit any overpayment to Deposit Account No. 50-0892.

Respectfully submitted,

April 5, 2002
Date

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PATENT TRADEMARK OFFICE

Exhibit A

Clean Version of The Pending Claims in U.S. Patent Application Ser. No. 09/735,712

1. (Amended) An isolated nucleic acid molecule comprising the nucleotide sequence of SEQ ID NO:1.

2. (Amended) An isolated nucleic acid molecule comprising a sequence that:

(a) encodes the amino acid sequence shown in SEQ ID NO: 2; and

(b) hybridizes under highly stringent conditions to the nucleotide sequence of SEQ ID NO: 1 or the complement thereof.

3. An isolated nucleic acid molecule comprising a nucleotide sequence that encodes the amino acid sequence shown in SEQ ID NO: 2.

4. An isolated nucleic acid molecule comprising a nucleotide sequence that encodes the amino acid sequence shown in SEQ ID NO: 8.

Exhibit B

Marked Up Version of Amended Claims in U.S. Patent Application Ser. No. 09/735,712

1. (Amended) An isolated nucleic acid molecule comprising [at least 24 contiguous bases of] the nucleotide sequence [first disclosed in the NHP polynucleotide described in] of SEQ ID NO:1.

2. (Amended) An isolated nucleic acid molecule comprising a nucleotide sequence that:

(a) encodes the amino acid sequence shown in SEQ ID NO:2; and

(b) hybridizes under highly stringent conditions to the nucleotide sequence of SEQ ID NO:1 or the complement thereof.

3. An isolated nucleic acid molecule comprising a nucleotide sequence that encodes the amino acid sequence shown in SEQ ID NO: 2.

4. An isolated nucleic acid molecule comprising a nucleotide sequence that encodes the amino acid sequence shown in SEQ ID NO:4.